

Appl. No. : 10/090,039
Filed : February 27, 2002

REMARKS

Applicants sincerely thank the Examiner for the courtesy she extended to Applicants' representatives during the personal interview of June 25, 2003, during which the pending Office Action and possible amendments to the claims were discussed. In view of the interview discussions, Applicants have hereby amended Claim 21 to recite the concentration relationship between the first and second buffers. In the amendments set forth above additions are underlined; there are no deletions. Applicants respectfully maintain that the amendments add no new matter and are fully supported by the specification as originally filed. Specific support for the amendments is found, inter alia, at page 15, lines 11-12.

The concentration relationship between the first and second buffers, as set forth in the amended Claim 21, better describes Applicants' invention. One of the concerns with having a growth medium to detect bacteria in the sample is the occurrence of false-negatives. A danger is that the high pH buffer may be of too large a concentration such that would delay a change of the pH of the solution due to the growth of bacteria and thereby delay the resultant color change. This may lead to a false negative reading. Another concern is that the low pH buffer is of small enough concentration that the color change affected would be transitory, as the pH of the solution reverts back to the higher pH by very slight environmental changes in the solution. Having the concentration ratio as claimed in the amended Claim 21 guarantees that a pH change of sufficient magnitude takes place with the growth of bacteria in the medium to produce a color change, and that the color change will remain visible long enough for the operator to detect.

Accordingly, Applicants respond below to the specific rejections and objections raised by the Examiner in the Office Action of April 17, 2003.

I. Rejections under 35 U.S.C. § 102(b)

Claims 21, 23-25, and 27 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by DiSorbo et al. (USP 5,474,931).

Applicants have amended Claim 21 to include a limitation defining the concentration relationship between the first and the second buffers. Claims 23-25 depend directly or indirectly from Claim 21 and, as such, incorporate all of its limitations. Claim 21 requires the concentration of the first buffer to be 1/10 to 1/100 the concentration of the second buffer. DiSorbo et al. does not include any such limitation.

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Applicants respectfully submit that since one of the limitations of Claims 21-26 is not disclosed in the cited references, the cited references do not anticipate the pending claims. Applicants respectfully request that the Examiner reconsider and withdraw the 102(b) rejection with respect to Claims 21 and 23-25.

With respect to Claim 27, Applicants respectfully traverse the 102(b) rejection. Claim 27 requires that the first pH range to be between 6.8 and 7.2. DiSorbo et al. discloses that the pH of its buffers range from 4.0 – 9.0. DiSorbo et al., column 10, lines 24-25. Thus, the pH range of Claim 27 is a specific range within a broad range disclosed by DiSorbo et al.

Recitation of a broad range in prior art does not necessarily anticipate the recitation of a narrow range in the claims. M.P.E.P. § 2131.03 states

In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with “sufficient specificity to constitute an anticipation under the statute.” * * * The question of “sufficient specificity” is similar to that of “clearly envisaging” a species from a generic teaching. See M.P.E.P. § 2131.02. * * * *The examiner must, in this case, provide reasons for anticipation* (Emphasis provided.)

Applicants respectfully submit that one of ordinary skill in the art cannot clearly envisage the pH range recited in Claim 27 from the pH range disclosed in DiSorbo et al. The pH range of 6.8 – 7.2 is very near neutral, covering only 0.2 pH points on either side of 7.0. This is a very narrow pH range specific for the growth of microorganisms. As those of skill in the art readily understand, growth of microorganisms is very much pH dependent. Applicants have identified a narrow pH range around pH of 7.0, which is particularly suitable for the purposes of the present invention.

By contrast, the pH range disclosed in DiSorbo et al. is very broad. It covers five pH points from 4.0, i.e., very acidic, to 9.0, i.e., very basic. There is no suggestion in DiSorbo et al. that a 0.4 point range, any 0.4 point range, in the pH is preferred. Thus, one of ordinary skill in art cannot clearly envisage a range of 0.4 pH points anywhere along the range of 4.0 – 9.0 as being particularly useful, let alone a 0.4 point range around 7.0. As directed by M.P.E.P., the Examiner must provide reasons for why a range of pH as broad as that disclosed in DiSorbo et al. anticipates the narrow range recited in Claim 27.

Applicants respectfully maintain that no reasons were provided for the anticipation of the claimed narrow range, and further submit that the claimed narrow range cannot be clearly

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envisaged from the broad disclosure of the cited reference. Therefore, Applicants respectfully submit that Claim 27 is not anticipated by the cited reference and request that the Examiner reconsider and withdraw the rejection.

II. Rejections under 35 U.S.C. § 103(a)

Claims 21, 22, and 26 stand rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over DiSorbo et al. (USP 5,474,931).

As mentioned above, Applicants have amended Claim 21 to include a concentration ratio limitation between the first and second buffers. This limitation does not appear in DiSorbo et al. In addition, the cited references, either alone or in combination, do not provide a suggestion or motivation to include the recited concentration limitation. Consequently, Applicants respectfully request that the Examiner reconsider and withdraw the rejection over DiSorbo et al..

Claims 21-27 stand rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over Japanese Pat. Appl. No. 07135984 A ("JP '984"), the translation of the abstract of which the Examiner kindly provided.

Once again Applicants refer to the concentration ratio limitation recited in the amended Claim 21. Applicants respectfully submit that JP '984 does not disclose, nor does it suggest, such a ratio limitation.

To be sure, JP '984 does teach a concentration ratio limitation. The abstract discloses that 1.2 g/L of sodium acetate, 0.348 g/L of K_2HPO_3 , and 0.224 g/L of KH_2PO_3 were included in the culture medium. Using the language of the currently pending claims, the phosphate buffer is equivalent to "the first buffer" and the acetate buffer is equivalent to the "second buffer." The ratio of the buffer concentrations in JP '984 is calculated as follows:

$$K_2HPO_3: \quad 0.348 \text{ g/L} \times 1/174.18 \text{ mol/g} = 2.0 \times 10^{-3} \text{ M}$$

$$KH_2PO_3: \quad 0.224 \text{ g/L} \times 1/136.08 \text{ mol/g} = 1.6 \times 10^{-3} \text{ M}$$

$$\text{Total phosphate:} \quad 2.0 \times 10^{-3} \text{ M} + 1.6 \times 10^{-3} \text{ M} = 3.6 \times 10^{-3} \text{ M}$$

$$\text{sodium acetate:} \quad 1.2 \text{ g/L} \times 1/82.03 \text{ mol/g} = 1.4 \times 10^{-2} \text{ M}$$

$$\text{Ratio of phosphate to acetate:} \quad 3.6 \times 10^{-3} \text{ M} / 1.4 \times 10^{-2} \text{ M} = \mathbf{0.26}$$

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Thus, the ratio disclosed in JP '984 is 2.6 – 26 times greater than the claimed ratio of about 1/10 to 1/100. The cited reference does not disclose the claimed ratio. Further, the Examiner has not pointed to a suggestion or motivation provided in the cited reference, either alone or in combination with other references or with the general knowledge in the art, to choose the claimed ratio. Therefore, Applicants respectfully submit that a *prima facie* case of obviousness with respect Claims 21-26 has not been established. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of Claims 21-26.

Applicants respectfully traverse the obviousness rejection of Claim 27. As discussed above, Claim 27 limits the pH range of the first buffer to between 6.8 and 7.2. The cited reference does not disclose, nor does it provide a suggestion or motivation, either alone or in combination with other references or with the general knowledge in the art, to choose the claimed pH range. Therefore, Applicants respectfully submit that a *prima facie* case of obviousness with respect Claim 27 has not been established. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of Claim 27.

Applicants respectfully maintain that claims are patentable and request that they be passed to issue. No fee is believed due in connection with this response. If this is incorrect, the Commissioner is hereby authorized to charge Deposit Account No. 07-0630. Applicants invite the Examiner to call the undersigned if any issues may be resolved through a telephonic conversation.

Respectfully submitted,

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